

**U.S. FOOD AND DRUG ADMINISTRATION**

NEW YORK DISTRICT

850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

HEF-35

Telephone: [718] 340-7000 [Ext 5301]

MAY 29 1997

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 51-NYK-97

Mr. Alfonso Conte, President
Conte Inc.
625 Green Lane
Union, N. J. 07083

Dear Mr. Conte:

Your firm has imported the following shipments into the United States:

<u>Sample No.</u>	<u>Entry No.</u>	<u>Date Entered</u>	<u>FDA Entered</u>
1778655	1011556629-0	11/4/96	11/7/96
1778659	1011554483-4	10/26/96	11/1/96
1778660	1011554341-4	10/25/96	11/1/96
1778661	1011554460-2	10/26/96	11/1/96
1778662	1011554473-5	10/26/96	11/1/96
1778663	1011554334-9	10/25/96	11/1/96
1778664	1011552746-6	10/22/96	11/1/96
1778665	1011551427-4	10/16/96	11/1/96
1778666	1011552369-7	10/23/96	11/1/96
1778667	1011552689-8	10/22/96	11/1/96
1778668	1011554532-8	10/26/96	11/1/96
1778669	1011554494-1	10/26/96	11/1/96
1778670	1011554319-0	10/25/96	11/1/96
1778671	1011553606-1	10/24/96	11/1/96
2035738	1011553598-0	10/23/96	11/1/96
2035739	1011553587-3	10/23/96	11/1/96
2035740	1011553583-2	10/23/96	11/1/96
2035741	1011550211-3	10/14/96	11/1/96
2035742	1011554312-5	10/25/96	11/1/96
2035822	1011554691-2	10/28/96	11/15/96

The above shipments all consisted of fresh vegetables which have a short shelf life. Notices of Location were issued after the Food and Drug Administration (FDA) received the entries.

Mr. Alfonso Conte, President
Conte Inc.

FDA received no response. FDA telephone the importer and resent the Location Notices. FDA has still received no response. In addition these shipments were not entered with the FDA until at least forty-eight (48) hours after the shipments entered the country and entry was made with U. S. Customs.

The FDA considers that these shipments were not made available by you for sampling. This is a violation of 21 CFR 1.90 which requires that the importer holds an entry intact pending receipt of the "May Proceed" or a Release Notice. A copy of the letter will also be sent to your Custom House Broker (Kuehne and Nagle) We are hereby requesting U. S. Customs to order redelivery of these shipments (copy inclosed).

Failure to promptly correct these violations may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of future shipments. It is your responsibility as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to prevent violations of this type.

Your written reply should be addressed to the Food and Drug Administration, attention:
Helen Jacobs
JFK Resident Post
Building 75, North Hangar Road
JFK International Airport
Jamaica, NY 11430

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Lillian C. Aveta", written over a large, loopy circular flourish.

Lillian C. Aveta
Acting District Director
New York District